

REMARKS

Claims 9, 10, 13-15, and 23-39 were pending in this application. Claims 10, 13 and 14 were withdrawn from consideration as being directed to non-elected subject matter. By this amendment, claims 9, 15, 24-36 and 38-39 are amended. Claims 23 and 37 are canceled. New claims 40-49 are added. Upon entry of this amendment, claims 9, 15, 24-36 and 38-49 are under consideration.

The amendments to claim 9 are supported in claims 15 and 23, and in the specification, for example, on page 4, fourth paragraph, page 9, second paragraph, page 9, first paragraph, lines 12-13, and on page 27, third paragraph. The amendments to claim 30 are supported in claims 37 and 39, and in the specification, for example, on page 4, fourth paragraph, page 9, second paragraph and on page 27, third paragraph. New claim 40 is supported on page 26, third paragraph. New claim 41 is supported on page 6, second paragraph and page 31, third paragraph. New claim 42 is supported on page 11, first paragraph. New claims 43-48 are supported on page 14, Table 1 and in the example section on pages 42-49. New claim 49 is supported on page 15, second paragraph. No new matter has been added by the foregoing amendments.

With respect to claim amendments and cancellation, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Withdrawn Rejections

Applicants acknowledge with appreciation the withdrawal of rejections of claims 9, 15, 23-29 under 35 U.S.C. §112, second paragraph and withdrawal of claims 30-39 under 35 USC §102 and §103.

Claim Rejections – 35 USC § 112, first paragraph

Claims 9, 15 and 23-29 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleges that the limitation “wherein said one or more 3’UTR sequence in said DNA expression vector and said one or more 3’UTR sequence in said control DNA expression vector are derived from the same gene” in claim 9 lack support in the specification.

Solely in an effort to expedite prosecution, claim 9, from which claims 15 and 23-29 depend, has been amended to delete this limitation. The rejection is thus rendered moot in view of the claim amendment.

Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claim Rejections – 35 USC § 112, second paragraph

Claims 30-39 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to recitation of the term “derived” in claim 30. The Examiner indicates that the word “derived” in claim 9, but not in claim 30, was deleted.

Solely in an effort to expedite prosecution, claim 30, from which claims 31-39 depend, has been amended to delete the word “derived.” The rejection is thus rendered moot in view of the claim amendment.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claim Rejections – 35 USC § 102

Claims 9, 24-27, 29-34 and 36-39 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Zubiaga et al. (“Zubiaga,” Molecular and Cellular Biology, Apr. 1995, p.2219-2230). Applicants respectfully traverse this rejection.

Solely in an effort to expedite prosecution, claim 9 has been amended by incorporating the limitation of claim 23, which has not been rejected under 35 U.S.C. § 102(b), to recite “a stably transfected cell line.” Similarly, claim 30 has been amended by incorporating the limitation of claim 37 to recite “a set of stably transfected cell lines.” Zubiaga does not teach stable transfection of cell lines.

Applicants further note that claims 9 and 30 have been amended to recite cell line(s) “used for screening compounds which affect mRNA stability.” Zubiaga is completely silent about this limitation.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

Claims Rejections – 35 USC §103***Zubiaga et al. in view of Banholzer et al.***

Claims 15 and 23 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Zubiaga et al. (“Zubiaga,” Molecular and Cellular Biology, Apr. 1995, p.2219-2230), in view of Banholzer et al. (“Banholzer,” Molecular and Cellular Biology, June 1997, p.3254-3260). Applicants respectfully traverse this rejection.

Claim 23 has been canceled, thus obviates the rejection. Applicants submit that Zubiaga and Banholzer, alone or in combination, do not render the amended claim 9 and its dependent claims (including claim 15) obvious.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reasons why the claimed invention would have been obvious. MPEP 2141. The Examination Guidelines for Determining Obviousness under 35 U.S.C. § 103 added in MPEP in view of the recent Supreme Court decision *KSR International Co. v. Teleflex*, 127 S. Ct. 1727 (2007), identifies seven rationales that can be used to support the legal conclusion of obviousness. MPEP 2141. One rationale identified in the Examination Guidelines is as follows:

G. Some Teaching, Suggestion or Motivation in the Prior Art That Would Have Led One of Ordinary Skill To Modify the Prior Art Reference or To Combine Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention.

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

MPEP 2143.

MPEP further provides that “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” MPEP 2143.03.

Zubiaga et al. focuses on identifying the minimal AU-rich motif capable of destabilizing mRNA. Various constructs were made and transiently transfected into NIH 3T3 cells. The stability of mRNA containing different sequences were evaluated and compared based on Northern blot analyses. Zubiaga is completely silent about stably transfected cell line(s). Neither does it suggest making of stably transfected cell line which is very labor-intensive and unnecessary for the purpose of Zubiaga. Zubiaga is also completely silent about using the cells for screening compounds which affect mRNA stability.

Banholzer et al. focuses on understanding the mechanisms by which rapamycin (“RAPA”), a known immunosuppressive drug, downregulates IL-3 mRNA in a tumor mast cell line. Genomic IL-3 wild-type sequences or a sequence lacking the AU-rich element (ARE) were transfected into separate tumor cell lines. The effects of rapamycin on the IL-3 mRNAs were evaluated. To determine whether the 3’UTR of IL-3 would confer sensitivity to a heterologous transcript, Banholzer et al. also examined the effect of rapamycin on AP reporter constructs carrying the 3’UTR of IL-3 with or without deletion of the ARE. They concluded that “IL-3 3’UTR could confer RAPA sensitivity to reporter transcripts, provided that the 3’UTR sequence was intact.” Banholzer thus conveys to a person of ordinary skill in the art that, for the purpose studying of the effect of rapamycin on IL-3 mRNA, it is important to keep the mRNA instability sequence in its natural state.

Banholzer is silent about a stably transfected cell line as recited in the amended claims. Neither does Banholzer teach or suggest a cell line comprising a DNA expression vector comprising a first DNA sequence having a heterologous instability sequence and a control DNA expression vector comprising a control DNA as recited in claim 9 and its dependent claims.

Further, Banholzer neither teaches nor suggests a heterologous instability sequence DNA that is heterologous to the 3’UTR sequence of the DNA expression vector. As discussed above, a person of ordinary skill in the art reading Banholzer would have understood that it is desirable to keep the mRNA instability sequence of IL-3 in its natural state, rather than inserting it artificially into a 3’UTR that is heterologous to the mRNA instability sequence.

Accordingly, Applicants respectfully submit that Zubiaga et al. and Banholzer et al. either alone or in combination, fail to teach or suggest all of the elements of claim 9 and its dependent claims, and as such, do not render claim 9 and its dependent claims obvious. Applicants respectfully request that the rejection be withdrawn.

Zubiaga et al. in view of Lemm and Ross

Claims 28 and 35 stand rejected under 35 §U.S.C. 103(a) as allegedly being unpatentable over Zubiaga et al. (Molecular and Cellular Biology, Apr. 1995, p.2219-2230) in view of Lemm and Ross (Molecular and Cellular Biology, June 2002, p.3959-3969).

As a preliminary matter, Applicants respectfully submit that claims 28 and 35 are amended to recite “a stably transfected cell line.” Applicants further note that Lemm and Ross was published after the priority date of the present application.

Applicants further submit that claims 28 and 35 are not rendered obvious by Zubiaga and Lemm and Ross. Zubiaga is discussed above. Lemm and Ross do not cure the deficiency of Zubiaga. Specifically, Lemm and Ross is cited as disclosing that a 249 nucleotide coding region from c-myc destabilizes c-myc and that such sequence destabilizes beta-globin mRNA when inserted in frame within the coding region of β -globin. Lemm and Ross do not teach or suggest stable cell lines or cell lines for screening compounds which affect mRNA stability.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **608352000100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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